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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,062	06/24/2003	Robert G. Urban	08191-004004	8636
7590	09/07/2005			
Janis K. Fraser Fish & Richardson P.C. 225 Franklin Street Boston, MA 02110-2804			EXAMINER SALIMI, ALI REZA	
			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/603,062	<b>Applicant(s)</b> URBAN ET AL.	
	<b>Examiner</b> A R. Salimi	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Response to Amendment***

The receipt of preliminary amendment of 6/24/2003 is acknowledged. Claims 21-69 have been canceled. Claims 1-20 are pending before the examiner.

### ***Priority***

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Please up-date the information by inserting the patent number for application no. 09/759,960.

### ***Claim Objections***

Claim 18 is objected to because of the following informalities: Claim is supposed to be only one complete sentence. Currently there is a period present after the parentheses of (SEQ ID NO: 20), which separates the claim from (SEQ ID NO: 4). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

Claims 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 12 is vague and indefinite because the intended metes and bounds of the first polypeptide is not defined. This affects the dependent claims.

Claim 18 is confusing and indefinite, the intended metes and bounds of the first polypeptide is not defined. In addition, the role or the significance of SEQ ID NO: 4 is not defined.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choo et al (J. of Virology, Feb. 1989, Vol. 63, No. 2, pages 782-789).

The claims are directed to immunogenic polypeptides of HPV E7 regions.

Choo et al characterized and disclosed a 26 amino acids long portion of the E7 protein of human papillomavirus type 16 (HPV-16) which is 100% identical to the now claimed invention SEQ ID NO: 16 (see the abstract, and Figure 12). This only differs since the claimed invention is directed to smaller protein fragment within Choo's et al teaching. One of ordinary skill in the art at the time of filing, however, would have been highly motivated by the above cited art to slightly modify the short polypeptide as taught by Choo et al to be utilized as an immunogenic composition to induce an immune response in a suitable host. The skill level in this art is rather

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high and it would have been within purview of a skilled artisan to slightly modify the disclosed protein by substituting an amino acids from either ends of protein of Figure 12 without changing its core character or its functionality principles. The skilled artisan having access to the above cited art would not have anticipated any unexpected results, as none have been provided. The core structure of immunogenic product as now claimed is for all-intense and purposes the same as taught by Choo et al. Therefore, the invention as a whole is prima facie obvious absent unexpected results.

Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choo et al (J. of Virology, Feb. 1989, Vol. 63, No. 2, pages 782-789), and Urban et al (WO 94/04557).

The claimed invention is directed to fusion proteins of first and second polypeptide linked via a peptide bond wherein the first peptide is capable of controlling the intercellular trafficking.

As sated above Choo et al taught a slightly larger portion of the immunogenic polypeptide fragment that is now claimed. Choo's et al teaching differs since they did not teach the trafficking control sequence.

Urban et al taught specifically SEQ ID NO: 18 as a trafficking sequence and it various permutations (see claims 16, and 20).

Therefore, one of ordinary skill in the art at the time of filing would have been motivated by the above cited art to fuse the core protein as taught by Choo et al to the trafficking sequence as taught by Urban et al to induce a an immunogenic in a suitable host wherein the trafficking

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sequence would control the intercellular trafficking of the immunogenic peptide of Choo et al so it be induce a more measured immune response, i.e. MHC I or II. The skilled artisan having access to the above cited art would not have anticipated any unexpected results, as none have been provided. The core structure of immunogenic product as now claimed is taught by Choo et al, the trafficking sequence is taught by Urban et al. Fusion of Choo's et al protein to Urban's et al sequence is notoriously obvious absent any unexpected results. Therefore, the invention as a whole is prima facie obvious absent unexpected results.

No claims are allowed.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

8/27/2005

  
ALI R. SALIMI  
PRIMARY EXAMINER